No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC., AND
TEVA PHARMACEUTICAL INDUSTRIES, RESPONDENTS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION TO CERTIORARI

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QUESTION PRESENTED

Whether this Court should review the Federal Circuit's factual conclusion that Helsinn's sale agreement with a third party publicly disclosed its claimed invention "in detail" (Pet. 33a) more than a year before it filed its patent application, thus triggering the "on sale" bar on patentability set forth in 35 U.S.C. §102(a).

CORPORATE DISCLOSURE STATEMENT

The parent companies of Respondent Teva Pharmaceuticals USA, Inc. are: Orvet UK Unlimited, Teva Pharmaceutical Holdings Cooperative U.A., Ivax LLC (f/k/a IVAX Corporation), Teva Pharmaceuticals Europe, B.V., and Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Pharmaceuticals USA, Inc.

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INTRODUCTION

This case involves the first Federal Circuit decision addressing the scope of the AIA's on-sale bar. Helsinn insists that the decision warrants immediate review because it "swept broadly" and was "'untethered to the statutory text.'" Pet. 33, 3. Yet Helsinn has presented a caricature of the decision, which not only is a unanimous, fact-bound ruling limited to "the circumstances involved" and "this particular [sales] [a]greement," but is grounded in the Patent Act's text, structure, and 200-year history. Pet. 20a, 43a.

Helsinn did not contest that history below. It conceded that "on sale" was a "term[] of art"—an "established term[]" that historically covered secret sales—and that even today the on-sale bar may be triggered without "disclosure of 'the details of the * * * invention.'" Beyond the vehicle problems created by these concessions, Helsinn asks this Court to second-guess the lower court's *factual* conclusion that the sale here was "public" rather than "secret." It thus turns out that the "question presented" is not really presented. Not surprisingly, no Federal Circuit judge supported en banc review—or even requested a vote.

Helsinn offers no convincing reason for this Court to grant review either. *First*, as to the ruling's scope, Helsinn criticizes the court below for stating that "if the existence of the sale is public, the details of the invention need not be publicly disclosed" to trigger the bar. Pet. 33. But the court did not just find that the *existence* of Helsinn's sale was public; it found that Helsinn disclosed the claimed drug formulation "in detail." Pet. 33a. The court declined to rule "more broadly than necessary," deferring any decision on "cases involv[ing] a public use where the invention

was not * * * disclosed" or "'secret sale' cases." Pet. 37a, 38a, 39a. Helsinn ignores this.

Helsinn also ignores that the government did not support en banc review, having stated at argument: "[I]f this Court concludes that this was in fact a sale that made the invention available to the public, that will not cause us any heartburn." That is what the court concluded. As Judge O'Malley explained, "the standard governing secret sales * * * simply is not implicated" here, and Helsinn's contrary view rests on the "mischaracterization[]" of "a single sentence." Pet. 4a, 6a n.1.

According to Helsinn, Judge O'Malley's opinion is "revisionist." Pet. 33. But in denying Helsinn's stay motion, the other two panel members fully endorsed her opinion, reiterating that the decision is "narrow." App., *infra*, 2a. Remarkably, Helsinn does not mention this order—or even provide it to the Court. But it confirms that this case is a poor vehicle to address the question presented, and that Helsinn and its pro-patentee amici seek review not to narrow a broad decision, but to broaden a narrow one.

Second, even if the sale here were secret, the decision was correct for additional reasons given by the panel and Judge O'Malley. Indeed, that Helsinn publicized its claimed formulation "in detail" (Pet. 33a) makes this an especially easy case. Helsinn's petition glosses over the statute's text, structure, and history —and its own concessions. "On sale" is a term of art with centuries of pre-AIA history; both its ordinary and specialized meanings include *all* sales, public and private. And "when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached." *Air Wis. Airlines Corp.* v.

Hoeper, 134 S. Ct. 852, 861–862 (2014). In fact, even before the on-sale bar existed, this Court held that the Patent Act and the Constitution barred commercially exploiting inventions before patenting them. *Pennock* v. *Dialogue*, 27 U.S. 1 (1829).

The AIA retained the term "on sale" unmodified, without limiting it to public sales, while embedding it in a list of bars that, by contrast, *do* repeatedly include the word "public." Those are powerful textual confirmations that Congress did not "work a foundational change in the theory of the statutory on-sale bar." Pet. 39a. "Congress generally acts intentionally when it uses particular language in one [part] of a statute but omits it in another." *Dep't of Homeland Sec.* v. *MacLean*, 135 S. Ct. 913, 919 (2015) (citations omitted). And as the court below observed, if Congress intended "a sweeping change" to the law, "it would do so by clear language" (Pet. 39a, 43a)—such as "*publicly* on sale."

Helsinn nonetheless insists that Congress worked just such a change—without amending "on sale"—by creating a new bar for claimed inventions "otherwise available to the public." According to Helsinn, "available to the public" is a "series modifier" that works backwards through the list of statutory bars, upending settled precedent as it goes. Pet. 15–16. But such a construction is proper only when the final clause "is applicable as much to the first and other words as to the last." *Paroline* v. *United States*, 134 S. Ct. 1710, 1721 (2014). As Judge O'Malley explained, §102(a)'s catchall clause is *not* as applicable "to the first and other words as to the last," since that reading would create massive "redundancies." Pet. 9a n.2. All the listed words except "on sale" are *already* inherently public or pre-labeled as public. Pet. 8a–9a & n.2.

Thus, the more natural reading is that, in adding "otherwise available to the public" to the statute, Congress confirmed that all public disclosures trigger the bar—even when made orally, or via new technologies. Congress did not shrink the distinct category of *sales* that invalidate patents.

Further, the AIA's next subsection distinguishes between "disclosures" and "public disclosures," which makes no sense if all §102(a) disclosures are public. Helsinn says the disclosures in §102(b) are "different" and "antecedent" (Pet. 19), but never says how. And as we will show, Helsinn's policy arguments fail on their own terms.

This Court is "a court of review, not of first view" (*Cutter* v. *Wilkinson*, 544 U.S. 709, 718, n.7 (2005)), and Helsinn presents a "secret sale" question that was not reached below. And since Helsinn's sale was invalidating under either view of that question, the answer does not matter. "[T]his Court reviews judgments, not opinions" (*Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984)), and both the panel's and Judge O'Malley's opinions support the judgment. Certiorari is not warranted to say which opinion is most powerful.

STATEMENT

A. The history of the on-sale bar

Helsinn briefly mentions the pre-AIA on-sale bar, but neglects its history. To understand the bar's current scope, however, it is vital to understand that beginning nearly 200 years ago—before the on-sale bar existed—this Court has repeatedly held that both the Patent Act and the Constitution bar commercially exploiting inventions before patenting them.

1. The 1790 and 1793 Patent Acts and this Court's decision in *Pennock*

Congress's first patent statute—the Patent Act of 1790—limited patents to matter "not before known or used." Ch. 7, §1, 1 Stat. 110. Similarly, the Patent Act of 1793 barred patenting matter "known or used before the [patent] application." Ch. 11, §1, 1 Stat. 319. Thus, the question arose early whether patents could cover inventions that had already been sold.

This Court addressed that question in *Pennock* v. *Dialogue*, 27 U.S. 1 (1829) (Story, J.). The patent there claimed a process of making hose with pressure-resistant joints. *Id.* at 3, 14. The joints did not reveal the process. But years before seeking a patent, the inventor authorized sales of the hose. *Id.* at 9. Thus, the defendant argued that the invention was "known or used before the application." *Id.* at 11–12.

The Court agreed. Inventions are "known or used" if "known or used by the public," and public use includes "sell[ing] [the] invention publicly." *Id.* at 19.

The Court stressed that allowing inventors to exploit inventions commercially before patenting them would violate not only the Patent Act, but the Constitution. The Patent & Copyright Clause authorizes Congress "'to promote the progress of science and useful arts, by securing *for limited times*, to authors and inventors, the exclusive right to their respective writings and discoveries,'" and "contemplates, therefore, that this exclusive right shall exist but for a limited period." *Id.* at 16–17 (quoting U.S. Const. Art. I, § 8, cl. 8). If inventors could profit from secret inventions, only to patent them later, it would "retard the progress of science":

> If an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention; if he should for a long period of years retain the monopoly, and make, and sell his invention publicly, and thus gather the whole profits of it * * * and then, and then only, when the danger of competition should force him to secure the exclusive right, he should be allowed to take out a patent * * * it would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries.

Id. at 19. Even before the on-sale bar, therefore, the law barred patenting inventions that had been publicly sold. *Id.* at 23; accord *Shaw* v. *Cooper*, 32 U.S. 292, 322–323 (1833); *Pfaff* v. *Wells Elec., Inc.*, 525 U.S. 55, 64 (1998). And as the Court later reaffirmed, "the inventor who designedly, and with the view of applying [his invention] indefinitely and exclusively for his own profit, withholds his invention from the public, comes not within the policy or objects of the Constitution or acts of Congress." *Kendall* v. *Winsor*, 62 U.S. 322, 328 (1858).

2. Congress adopts the on-sale and public use bars in 1836

The Patent Act of 1836 continued to bar patenting inventions "known or used by others." Ch. 357, §6, 5 Stat. 117. But Congress also added language barring patents on inventions that were "in public use or on sale." *Ibid.* These distinct restrictions are now known as the "public use" and "on sale" bars.

Early on, this Court read "public use" to bar patenting where "an inventor, having made his device, gives or sells it to another, to be used * * * without

limitation or restriction, or injunction of secrecy." *Egbert* v. *Lippmann*, 104 U.S. 333, 336 (1881). "[S]uch use is public, even though the use and knowledge of the use may be confined to one person" and the invention "cannot be seen or observed by the public eye." *Ibid.* (invalidating a patent on a corset stay previously worn under a woman's dress).

Unlike items in "public use," however, items "on sale" have never had to be sold publicly to defeat patentability. As then-Judge Stevens once explained, "the 'public use' and the 'on sale' objections" are "distinct"; "[t]here may be a public use prior to any sale," and, "alternatively, there may be sales which neither the vendor nor the purchaser desires to make public but which nevertheless" trigger the bar. *Dart Indus., Inc.* v. *E. I. Du Pont De Nemours & Co.*, 489 F.2d 1359, 1364 n.8 (7th Cir. 1973). Following this approach, courts have consistently invalidated patents on commercially exploited inventions.

The leading lower-court case is *Metallizing Engineering Co.* v. *Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), which this Court endorsed in *Pfaff*. 525 U.S. at 68. As Judge Learned Hand explained, an inventor "shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." *Ibid.* (quoting *Metallizing*, 153 F.2d at 520). This rule "had its origin" in *Pennock*'s holding that "it would materially retard the progress of science" if inventors could profit from their inventions while "hold[ing] back from the knowledge of the public the secrets [thereof]." 153 F.2d at 520, 518 (quoting *Pennock*, 27 U.S. at 19). And the rule applies "regardless of how little the public may have learned about the invention." *Id.* at 520.

Following *Pennock* and *Metallizing*, myriad courts have held that the on-sale bar reaches confidential sales.[1] As these courts recognize, "[t]he primary policy underlying the 'public use' case is that of detrimental public reliance, whereas the primary policy underlying an 'on-sale' case is that of prohibiting the commercial exploitation of the design beyond the statutorily prescribed time period." *Cont'l Plastic Containers* v. *Owens Brockway Plastic Prods., Inc.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998). Thus, "[a]ny attempt to use [an invention] for a profit * * * for a longer period than [one year] before the application, would deprive the inventor of his right to a patent." *Pfaff*, 525 U.S. at 65 (citation and emphasis omitted).

Helsinn thus conceded below that "on sale" was a "term[] of art" under pre-AIA law—an "established term[]" that has always appeared in a list of "public" activities, yet captured secret sales. C.A. Br. 41.

3. In the AIA, Congress considers removing the on-sale bar, but declines to do so

In 2011, Congress passed the AIA. Previously, the Act provided that "[a] person shall be entitled to a patent unless":

> the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application[.]

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[1] Pet. App 35a n.7, 40a (collecting cases); *Medicines Co.* v. *Hospira, Inc.*, 827 F.3d 1363, 1376–1377 (Fed. Cir. 2016) (en banc) (same); *Mfg. Research Corp.* v. *Graybar Elec. Co.*, 679 F.2d 1355, 1362 (11th Cir. 1982); *Hobbs* v. *U.S. Atomic Energy Comm'n*, 451 F.2d 849, 860 (5th Cir. 1971).

35 U.S.C. §102(b) (2010).

For several years, Congress considered removing the on-sale bar, thus eliminating "secret activities as grounds for invalidity." 154 Cong. Rec. 22,631 (2008) (Sen. Kyl). For example, in 2005, Congress considered stating:

> (1) the claimed invention was patented, described in a printed publication, or otherwise publicly known[.]

H.R. 2795, 109th Cong.; see also, *e.g.*, S. 3818, 109th Cong.; S. 3600, 110th Cong. These versions failed.

The AIA, however, restored the term of art "on sale" to the statutory list. Today, "[a] person shall be entitled to a patent unless":

> the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention[.]

35 U.S.C. §102(a) (2011).

B. The invention, the publicized agreement for its sale, and the district court's ruling

Helsinn's '219 patent, issued in 2013, claims a low-dosage form of palonosetron, a drug long used to treat chemotherapy-induced nausea and vomiting. In 2001, over a year before the relevant patent application, Helsinn contracted with MGI Pharma "to distribute, promote, market, and sell" Helsinn's later-patented "0.25 mg and 0.75 mg palonosetron products," or "whichever" dosage FDA approved. Pet. 29a, 23a.

MGI disclosed the sale, and a partially redacted copy of the Agreement, to the SEC. Pet. 5a. Together, the parties publicly announced the Agreement, which "described the claimed drug formulation 'in detail.'" *Ibid.* (quoting Pet. 33a). Only the drug's "price" and "specific dosage[s]" were not publicly disclosed. Pet. 24a.

When Helsinn sued Teva, Teva answered that the MGI Agreement triggered the on-sale bar. The district court agreed that the Agreement "was a contract for a future commercial product." Pet. 164a. Nevertheless, it deemed the on-sale bar inapplicable, reasoning that the invention was not "ready for patenting" or "available to the public." Pet. 210a, 180a.

C. The Federal Circuit finds the invention "on sale" under the particular agreement and circumstances involved here

Teva appealed, invoking the AIA's text, structure, and history. Helsinn rejoined that the legislative history was "authoritative," complaining that "Teva denounce[d] [it]." C.A. Br. 50, 53 (citations omitted). Helsinn cited "the additional statutory language" ("otherwise available to the public"), numerous floor statements, and various committee reports. Pet. 37a; C.A. Br. 50–58.

The panel reversed, finding the invention "overwhelming[ly]" ready for patenting. Pet. 47a. Further, the panel held that, under the UCC, the Agreement "constituted a sale of the claimed invention—the 0.25 mg dose—before the critical date." Pet. 43a. The Agreement "described the palonosetron formulation in detail and Helsinn does not assert that the 0.25 mg dose described in the [MGI] Agreement does

not embody the asserted claims." Pet. 33a. Helsinn does not contest these rulings.

The court also held that the sale triggered the on-sale bar. In so holding, it emphasized that it "d[id] not find that distribution agreements will always be invalidating," just "that this particular Supply and Purchase Agreement is." Pet 43a. Helsinn had both publicly announced its sale and described the claimed formulation "in detail." Pet. 33a. The court concluded that the AIA "did not change the statutory meaning of 'on sale' in the circumstances involved here" (Pet. 20a), adding that, even if Helsinn had not disclosed the invention in detail, Congress would use "clear language" if it intended "a sweeping change to our on-sale bar jurisprudence" (Pet. 43a).

As to Helsinn's "floor statements," the court noted that they are "typically not reliable." Pet. 36a. Regardless, the statements nowhere suggested that Congress overruled the numerous decisions "explicitly reject[ing] a requirement that the details of the invention be disclosed." Pet. 40a. Helsinn's sale thus triggered the on-sale bar.

D. The Federal Circuit unanimously denies rehearing

Helsinn sought rehearing, but no judge requested a vote and review was denied. Judge O'Malley concurred, emphasizing the narrowness of the decision, providing additional "principles of statutory interpretation" that support it (Pet. 9a–12a), and correcting Helsinn's "mischaracterizations" thereof (Pet. 4a–7a).

As Judge O'Malley observed, Helsinn mischaracterized the decision by suggesting that: (1) the on-sale bar will be triggered "every time the fact of a sale is disclosed to the public"; (2) "all supply-side agree-

ments with third-party distributors will constitute invalidating transactions"; and (3) "our holding is inconsistent with our en banc decision in *Medicines Co.* v. *Hospira*, 827 F.3d 1363 (Fed. Cir. 2016)." Pet. 4a. As she explained, the decision "does not suggest that publicly announced agreements will always trigger the on-sale bar," or "that secret sales never will." Pet. 4a–5a. Rather, "the confidential nature of a transaction is just one of several factors" in a "fact-intensive" analysis, and "[a]ll that our panel opinion held was that the particular agreement at issue triggered the on-sale bar, in part—but not exclusively—because it was made public." Pet. 5a, 6a.

Judge O'Malley also noted that Helsinn made "few legal arguments" to support its interpretation. Pet. 8a. "Helsinn's only argument directed to the text" was "that the new phrase 'or otherwise available to the public'" modifies "'on sale,'" but that reading had "several problems." *Ibid.* For example, such "series modifiers" work only when the modifier "appli[es] as much to the first and other words as to the last"; but "otherwise available to the public" is "not equally applicable to all preceding phrases because each phrase * * * recites a disclosure that is necessarily public. Helsinn's reading * * * would therefore create redundancies." Pet. 9a & n.2.

Numerous other factors confirmed "that Congress meant to leave the on-sale bar intact." Pet. 9a. For instance, "Congress chose not to modify the term 'on sale,'" confirming that it "intended for that term to take on the meaning that courts had attributed to it for well over a century." *Id.* at 9a–10a. Further, §102(b)(1) refers to both "disclosures" and "public disclosures"; but "[i]f all prior art events—i.e., all 'disclosures'—recited in §102(a) were already public disclo-

sures, the word "publicly * * * would be redundant." Pet. 10a–11a. In short, "[a]s the panel opinion noted, '[i]f Congress intended to work such a sweeping change to our on-sale bar jurisprudence * * * it would [have done] so by clear language,'" not in a manner "at odds with so many principles of statutory interpretation." *Ibid.*

Helsinn moved to stay the mandate. In its order denying the stay, which Helsinn omits from its appendix, the panel endorsed "the reasons set forth" in "Judge O'Malley's concurrence" and reiterated that "the decision is a narrow one." App., *infra*, 2a. The Chief Justice likewise denied a stay. 17A785. Teva has since launched generic palonosetron.

REASONS FOR DENYING THE PETITION

I. Certiorari should be denied because the decision below is narrow, fact-bound, and rife with vehicle problems.

According to Helsinn, this case "involves a secret sale" and the decision below "swept broadly." Pet. 22, 33 (quoting Pet. 43a). Both contentions require ignoring much of what the Federal Circuit actually said, and Helsinn's own concessions. The decision below is expressly narrow, fact-bound, and confined to the unusual circumstances here; and it is the first to interpret the AIA's on-sale bar. Further, the petition rests on a *factual* challenge to the court's conclusion that Helsinn's sale was public—a major vehicle problem. Even if the court had incorrectly resolved that issue, its decision would not warrant certiorari. Not surprisingly, no judge below supported rehearing.

A. The Federal Circuit limited its decision to the unusual agreement here and declined to reach the secret-sale issue.

Judge O'Malley explained that "[a]ll that our panel opinion held was that the *particular* agreement at issue triggered the on-sale bar." Pet. 5a. By Helsinn's lights, that represents only Judge O'Malley's view. Pet. 13, 33. Helsinn is mistaken.

First, in language that Helsinn never mentions, the court limited its ruling to "the circumstances involved here" and "this particular * * * Agreement." Pet. 20a, 43a. "We do not find that distribution agreements will always be invalidating under § 102," the court held. Pet. 43a. "We simply find that this particular Supply and Purchase Agreement is." *Ibid.* The court declined "to decide this case more broadly than necessary," purposely not reaching "cases involv[ing] a public use where the invention was not * * * disclosed to the public" or "'secret sale[s].'" Pet. 37a, 38a, 39a. Helsinn ignores these passages. But even its own amicus below admitted that the court "cabin[ed] the decision to the facts." Dkt. 166 at 4.

Second, the court's reasoning follows from Helsinn's unique distribution agreement, its extensive disclosures, and its exploitation of its product. Explaining that patentees "must unambiguously place the invention on sale, as defined by the patent's claims," the court observed: "that is clearly the case here." Pet. 33a. Helsinn did not merely publicize the sale's *existence*; the sale documents "described the claimed drug formulation 'in detail.'" Pet. 5a (quoting Pet. 33a). As Judge O'Malley elaborated:

> Helsinn did not just disclose the fact that it had entered into a supply agreement with MGI; a par-

> tially-redacted copy of the Agreement itself was included with MGI's Form 8-K filing. As the panel noted, the Agreement described the claimed drug formulation "in detail." The Agreement also "expressly contemplated" the passage of title, and made clear that Helsinn "commercially marketed its invention before the critical date."

Ibid. (citations omitted).

In other words, that a sale is "publicly announced" is "not dispositive." Pet. 5a. Rather, courts must also consider "the nature of the disclosure"—a "fact-intensive" inquiry. Pet. 4a, 6a. Thus, to "suggest that publicly announced agreements will always trigger the on-sale bar" is a "mischaracterization[]" based "on a single sentence.'" *Id.* at 4a. Helsinn and its amici repeat the mischaracterization here.

Third, Helsinn never mentions that the full panel endorsed Judge O'Malley's concurrence. In denying Helsinn's motion for a stay pending certiorari, the panel explained: "For the reasons set forth in the majority opinion, and in Judge O'Malley's concurrence to the denial of rehearing, the decision is a narrow one." App., *infra*, 2a. Yet Helsinn accuses Judge O'Malley of "revisionis[m]" without acknowledging the stay order—or even including it in its appendix. Pet. 33. And since that order speaks directly to whether the ruling below is "narrow," Helsinn's omission contravenes Rule 14.1(i)'s mandate that the appendix "shall contain" all "relevant opinions [and] orders."

Finally, no judge even requested a poll on rehearing en banc. Helsinn says the on-sale bar "'is probably the greatest source of litigation involving * * * challenges to patent validity.'" Pet. 28 (citing Mueller, *Patent Law* 263 (5th ed. 2016)). But the full

quotation says "*35 U.S.C. §102(b) (2006)* challenges"—meaning pre-AIA challenges including often-litigated issues such as anticipation. And even as to the on-sale bar, the author explains that "many" of the pre-AIA cases addressed "what state of development the invention must be in"—which has nothing to do with whether the invention is on sale. Mueller, *supra*, at 265.

Further, in the years since the AIA passed in 2011, this case "provid[ed] the * * * first potential opportunity to determine whether the AIA changed the law of on sale bar." *Id.* at 333 n.375. It is thus fanciful to call review "urgent." Pet. 29. Future Federal Circuit panels remain free to resolve the question Helsinn (incorrectly) says is presented here. Rather than credit the prognostications of Helsinn and its amici, this Court should let that question percolate.

B. This case is a poor vehicle to decide the scope of the AIA's on-sale bar.

The opinions below confirm that this case is a poor vehicle to address the question presented. Yet Helsinn ignores both the court's narrowing language and Helsinn's concession that inventions may be on sale without "disclosure of 'the details.'" Pet. for Reh'g En Banc 10.

1. The court concluded that Helsinn's sale was public, and the petition contests that factual determination.

a. Having found that this case involves a public sale, the court below "decline[d] to address" "cases [that] involved a public use where the invention was not * * * disclosed to the public," or "'secret sale' cases." Pet. 38a, 39a. These passages place in proper context the court's statement that "if the existence of

the sale is public, the details of the invention need not be publicly disclosed" to trigger the bar. Pet. 33. As Judge O'Malley explained, the decision below did not turn on this "single sentence," and "the standard governing secret sales * * * simply is not implicated" here. Pet. 4a, 6a n.1. In short, the court found that the sale was public, and there will be time enough for this Court to address secret sales where actually presented in a future case.

Helsinn's petition thus challenges the court's *factual* conclusion that the sale here was "public," not "secret." Pet. 22 (this case "involves a secret sale"). Attempting to avoid this difficulty, Helsinn suggests that Teva "conceded that 'the allegedly invalidating sale at issue did not make the invention publicly available.'" Pet. 11, 22 (citation omitted). But Teva conceded no such thing, and Helsinn's assertion is supported only by a citation of *the government's* brief. Teva has consistently contended not only that the bar may be triggered by *either* public or secret sales, but that "even if the on-sale bar under the AIA does include a 'public' requirement—which it does not—the Supply and Purchase Agreement still constitutes an invalidating offer for sale." *E.g.*, Dkt. 312 at 3 (D.N.J.); see *ibid.* ("the plain fact is that the commercial contract between Helsinn and MGI was 'public'"); Pet. 151a ("Teva additionally argues that Helsinn violated the on-sale bar even under Helsinn's proposed interpretation of the AIA, as the supply agreement was publicized and MGI is a member of the public."); C.A. Reply Br. 12. And even if the court below had erred in resolving that issue, review is not warranted to correct "erroneous factual findings." Rule 10.

b. Nor does the ruling here portend "uncertainty" at the PTO. Pet. 28. Helsinn never mentions it, but

the government, after participating at the panel stage, did not support en banc review. That is not surprising. The PTO's guidance, which lacks the force of law, states only that a "secret sale or use activity does not qualify as prior art" (78 Fed. Reg. 11062 (Feb. 14, 2013)); and the court below found that the sale "described the claimed drug formulation 'in detail.'" Pet. 5a (quoting Pet. 33a).

As the government's counsel stated at argument below, "if this Court concludes that this was in fact a sale that made the invention available to the public, that will not cause us any heartburn."[2] That is what the court concluded. But even if it had reached the secret-sale question, it would not have been disruptive to hold that "on sale," a term of art, still covers nonpublic sales.

2. Below, Helsinn forfeited key points that it asks this Court to take up.

Helsinn's positions below further confirm that this case is anything but an "ideal vehicle" to resolve the question presented. Pet. 32. For example, Helsinn complains that the court below "completely ignored" the statutory definition of "claimed invention" (Pet. 22), while ignoring that Helsinn *never cited it*.

But it is worse than that. Helsinn affirmatively disclaimed the position "that an invalidating offer requires disclosure of 'the details of the * * * invention.'" Pet. for Reh'g En Banc 10. According to Helsinn, to trigger the on-sale bar, disclosing "the *existence*" of the sale was not enough, disclosing "the *details*" of the invention was more than enough, and disclosing the claimed invention without the details

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[2] https://bit.ly/2I8s3bo (minute 32:52–33:10).

was just right. Helsinn now abandons its "Goldilocks" theory—demanding that every detail of "the claimed invention" be disclosed (Pet. 22) and assailing the statement that "if the existence of the sale is public, the details of the invention need not be publicly disclosed" (*id.* at 43a). Pet. 4, 12–13, 21, 32–33. Helsinn should be held to its position below.

Regardless, Helsinn neglects portions of the opinions below explaining how the sale documents here "described the claimed drug formulation 'in detail'" (*id.* at 5a (quoting Pet. 33a)) and "constituted a sale of the claimed invention" (Pet. 43a). Such passages confirm that Helsinn faults the Federal Circuit's *application* of its legal framework to these facts, not the framework itself. Review should be denied.

II. Certiorari should also be denied because, whether public or secret, the invention here was on sale.

Certiorari should also be denied because, whether the sale here was "public" or "secret," the decision below is firmly grounded in the AIA's text, structure, history, and purpose. See *Chevron*, 467 U.S. at 842 ("this Court reviews judgments, not opinions").

A. The AIA's plain text confirms that Congress did not change the settled meaning of "on sale," which Helsinn conceded was a term of art.

1. Under the on-sale bar's plain terms, offering to sell an invention will start the one-year clock to apply for a patent regardless of whether the offer discloses all "details." Pet. 40a–43a. A "sale" is a "transfer of property for money or credit" (*Random House Webster's Unabridged Dictionary* 1693 (2d ed. 2001)), a definition that covers private transfers; and myriad

courts so held before the AIA. And as the court below recognized: "If Congress intended * * * a sweeping change to our on-sale bar jurisprudence," "it would do so by clear language." Pet. 43a.

After all, Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman* v. *Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001). Yet if Helsinn is correct, Congress "hid[] an awfully big elephant in a tiny mousehole," as it reads "a 'residual clause' and a few passages of legislative history to overturn nearly two centuries of consistent U.S. patent policy." Merges & Duffy, *Patent Law and Policy* 360 (7th ed. 2017). As Helsinn's own authority admits, "the AIA did not sub silentio overrule th[is] well-established case law." Mueller, *supra*, at 331.

By adding "otherwise available to the public" to §102, Congress simply confirmed that patents will always be barred by public disclosures—even if made orally, or via new technologies, rather than, as before, in a "printed publication." The lower courts were divided on that question, so Congress had reason to address these "known unknowns." See, *e.g.*, *In re Klopfenstein*, 380 F.3d 1345, 1349 n.4 (Fed Cir. 2004) (oral presentations); *Diomed, Inc.* v. *Angiodynamics, Inc.*, 450 F. Supp. 2d 130, 141 (D. Mass. 2006) (video).

Although Helsinn never mentions it, Helsinn conceded below that "on sale" was a "term[] of art"—an "established term[]" that has always been listed together with "public" activities, yet also captured non-public sales. C.A. Br. 41. The court agreed, citing numerous authorities. Pet. 35a n.7, 39a–43a. And if

"on sale" covers confidential sales, the claimed invention need not be made public.

This reading is hardly "untethered to the statutory text" (Pet. 3); it reflects the natural, historic meaning of "on sale." After all, "when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached." *Hoeper*, 134 S. Ct. at 861–862. Had Congress wished to overrule settled law, it could have said "publicly on sale." Including some form of the word "public" is how Congress limited the surrounding bars, and "Congress generally acts intentionally when it uses particular language in one [part] of a statute but omits it in another"—particularly where, as here, the disparate terms appear "in the same sentence." *MacLean*, 135 S. Ct. at 919. Further, public sales are already covered by the public use bar. *E.g.*, *Egbert*, 104 U.S. at 336 (selling "to another * * * without limitation" is public use).

2. Helsinn's sole textual response—that "otherwise available to the public" is a "series modifier" restricting the whole list to public activities (Pet. 15–16)—creates glaring redundancies. A clause is a series modifier only if it "is applicable as much to the first and other words as to the last." *Paroline*, 134 S. Ct. at 1721. But as Judge O'Malley explained, §102(a)'s catchall clause is *not* equally applicable "to the first and other words as to the last," because all the words except two—"on sale"—are inherently public or pre-labeled as public. Pet. 8a–9a & n.2.

The AIA bars a patent if the invention "was *patented*, described in a printed *publication*, or in *public* use, on sale, or otherwise available to the public" (emphases added). "Patented" needed no modification because "[p]atents are public records." *Boyden* v.

Burke, 55 U.S. 575, 582 (1852). So too with "printed *publications*" and items "in *public* use." *Klopfenstein*, 380 F.3d at 1348 ("the key inquiry" is whether references are "'publicly accessible'"). To read "otherwise available to the public" as modifying these terms creates "hopeless[] redundan[cies]." *Lockhart* v. *United States*, 136 S. Ct. 958, 965 (2016)). And a clause is not a series modifier where "it takes more than a little mental energy to process the individual entries in the list, making it a heavy lift to carry the modifier across them all." *Id.* at 963.

According to Helsinn, *United States* v. *Standard Brewery, Inc.*, 251 U.S. 210 (1920), shows otherwise. Pet. 16. The items listed there, however, were not pre-labeled. Rather, the statute referred to "beer, wine, or other intoxicating [beverages]." 251 U.S. at 218. For that statute to be analogous to §102(a), it would have to refer to "intoxicating wine"; and "beer" would have to be a term of art that captured nonalcoholic beer. That is the situation here, where multiple terms are pre-labeled "public" and "on sale" is a term of art covering nonpublic sales.

3. Recognizing these textual difficulties, Helsinn initially omits "patents" and "described in a printed publication" from its quotation of the statute (Pet. 4), but ultimately concedes that such disclosures "are, by their very nature, publicly available." Pet. 15. Not to worry, says Helsinn—the backwards work of "otherwise available" stops abruptly at the "or" in the series, such that the modifier applies only to a subseries in the list—which Helsinn dubs "the final three-item series." Pet. 18 n.4. But that is just the kind of mental gymnastics that show why §102(a)'s catchall clause is not a series modifier. Carrying the modifier

across the list is such a "heavy lift" (*Lockhart*, 136 S. Ct. at 963) that Helsinn must cut down the list.

Even this drastic measure, moreover, cannot save Helsinn's interpretation. Because items in "public use" are already public, applying "otherwise available to the public" to Helsinn's preferred subseries creates a "hopeless[] redundan[cy]" (*id.* at 965)—"in public use available to the public." Helsinn answers that, before the AIA, "public use" was interpreted "to include certain types of secret uses." Pet. 17. Not so. This Court's longstanding test for "public use" is providing "to another * * * without limitation or restriction"—"such use is public." *Egbert*, 104 U.S. at 336. And if "public use" covered secret uses, it would be odd for Congress to change the statute's meaning by repeating that very word ("public") in a later catchall phrase.

No matter how Helsinn slices §102(a), it cannot make "on sale" mean "*publicly* on sale." Congress did not say that. And Helsinn's contrary reading—that Congress changed a term of art with a carom shot, by adding a later catchall phrase—creates incurable "redundancies." Pet. 8a–9a & n.2 (O'Malley, J.).

4. Rather than modifying the preceding series, the catchall phrase in §102(a) falls within the default rule that a "limiting clause" applies "only to the last antecedent." *Barnhart* v. *Thomas*, 540 U.S. 20, 27 (2003). That is, "to the public" limits only "otherwise available." Helsinn says the issue "is not whether 'to the public' modifies 'otherwise available' (it does), but whether the whole phrase "or otherwise available to the public" informs the meaning of the two parallel phrases that precede it (again, it does)." Pet. 17. But *Barnhart* rejected an indistinguishable attempt to

rewrite the first half of a sentence based on a modifier attached to the second half. Like Helsinn's reliance on "otherwise," the argument in *Barnhart* depended on over-reading the word "other."

Barnhart involved a catchall clause in a statute governing disability benefits:

> An individual shall be determined to be under a disability only if * * * he is not only unable to do his previous work but cannot * * * engage in any other kind of substantial gainful work which exists in the national economy[.]

42 U.S.C. §423(d)(2)(A). The agency refused to label an applicant disabled because she could do her previous work, declining to inquire whether that work still "exist[ed] in the national economy." 540 U.S. at 22. That is, the agency would not read "which exists in the national economy" to modify "previous work." *Id.* at 22–23.

This Court sided with the agency, holding that the "limiting clause" ("which exists in the national economy") applied only to the "last antecedent" ("any other kind of substantial gainful work"). 540 U.S. at 26. In so holding, the Court followed precedent that similarly read another catchall clause. *Ibid.* (citing *FTC* v. *Mandel Bros.*, 359 U.S. 385, 389 & n.4 (1959), which held "that the 'limiting clause is to be applied only to the last antecedent,'" which did not include any item in the preceding list). This was not just a matter of deferring to the agency; the Court endorsed the agency's reasoning with an illustration of its own.

Specifically, the Court cited "the case of parents who, before leaving their teenage son alone in the house for the weekend, warn him, 'You will be punished if you throw a party or engage in any other ac-

tivity that damages the house.'" 540 U.S. at 27. The Court continued: "If the son nevertheless throws a party and is caught, he should hardly be able to avoid punishment by arguing that the house was not damaged. The parents proscribed (1) a party, and (2) any other activity that damages the house. As far as appears from what they said, their reasons for prohibiting the home-alone party may have had nothing to do with damage to the house—for instance, the risk that underage drinking or sexual activity would occur." *Ibid.* "And even if their only concern was to prevent damage," the parents "might have wished to preclude all argument," "by specifying and categorically prohibiting the one activity—hosting a party—that was most likely to cause damage." *Id.* at 28.

As in *Barnhart* and *Mandel*, the phrase "to the public" modifies only the last antecedent—"otherwise available." Congress had powerful reasons for withholding patents on items "on sale" privately; otherwise, inventors could extend their monopolies by gaming the system. *Infra* at 30–32. And even if Congress aimed only to encourage inventors to publicize their discoveries, Congress may have wished to preclude all argument by categorically barring patents after all sales, public or private. Certiorari is unwarranted.

B. Helsinn has no answer for §102(b), which expressly distinguishes between public and private disclosures.

Helsinn's reading of §102(a) also runs headlong into the Act's next subsection—which distinguishes between "disclosures" and "public disclosures." Specifically, §102(b)(1) creates "[e]xceptions" to §102(a)—including a grace period whereby "[a] disclosure made

1 year or less before" the filing date "shall not be prior art" if either "(A) the disclosure was made by the inventor"; or "(B) the subject matter disclosed had, before such disclosure, been *publicly disclosed* by the inventor." (Emphasis added.) Thus, an inventor's "['disclosure'] will not bar her from patenting * * * within a year after that disclosure"; and an inventor's "'public disclosure'" immunizes her filing "from all prior art, not just [her own]." Lemley, *Does "Public Use" Mean the Same Thing It Did Last Year?*, 93 Tex. L. Rev. 1119, 1128 (2015).

If, as Helsinn posits, all §102(a) disclosures are "public," then distinguishing between "disclosures" and "public disclosures" is incoherent. But if "'public use' and 'on sale' have the same meaning they have always had"—if "on sale" captures confidential sales —"the distinction between disclosures and public disclosures makes sense." *Ibid.* Why? Because "'disclosures' means all types of 'prior art'"—"includ[ing] some that are not public." *Ibid.*; see 42 Intellectual Property Professors' C.A. Amicus Br. (Dkt. 43) 2–5.

Further, the distinction between "public disclosures" and "disclosures" goes to §102(b)(1)'s "animating principle"—namely, that "to earn a grace period as against a third party who has begun to bring an invention to the attention of the public, an inventor must confer some benefit on the public." Merges, *Priority and Novelty Under the AIA*, 27 Berkeley Tech. L.J. 1023, 1042 (2012). And that benefit must be "a full-on public disclosure." *Ibid.* Helsinn's reading thus guts "the essence of the new third-party grace period." *Ibid.*; see Merges & Duffy, *supra*, at 360–361.

Helsinn and its amici have no comprehensible answer. Helsinn speculates as to why "Congress did *not*

use the word 'publicly'" in parts of §102(b). Pet. 19 (emphasis added); see *ibid.* ("Congress had no need to use the term 'public' to describe those disclosures"). Yet Helsinn never explains why Congress *did* refer to "public disclosure[s]"—except to say that such disclosures are "different" and "antecedent." Pet. 19. How? Helsinn never says. Instead, it declares that "the term 'public[]' in that provision does nothing to undermine the proposition that all Section 102(a)(1) prior art must be 'available to the public.'" Pet. 19-20. That is merely a conclusion.

Helsinn postulates that a mere "disclosure" (unlike a "public disclosure") might refer to patent applications. Pet. 20 n.5. But Congress devoted the very next subsection (§102(b)(2)) to the effect of "Disclosures appearing in applications and patents." That subsection would be superfluous if §102(b)(1) captured such applications.

In short, Helsinn's reading gives no meaning to "public disclosure." That violates the "fundamental canon" that "the words of a statute must be read in their context and with a view to their place in the overall statutory scheme"—as a "coherent," "harmonious whole." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (quotations omitted).

C. Congress repeatedly declined to adopt bills that did what Helsinn wishes.

The AIA's drafting history further supports the decision below, as Congress repeatedly rejected bills that did what Helsinn wishes. Ignoring this, Helsinn calls the decision below "indefensible," "profoundly flawed," and "outmoded" (Pet. 15, 34) for considering floor statements. But it was *Helsinn* that said "[the court] should look to the floor statements." Pet. 36a.

And both the drafting history and floor statements support the decision below.

1. As Judge O'Malley observed, "Congress several times considered, but rejected, the very changes to the on-sale bar Helsinn urges us to conclude were actually made." Pet. 12a. Early bills proposed repealing the on-sale bar, thus "eliminating confidential sales" as "grounds for invalidity." 154 Cong. Rec. 22,631 (2008) (Sen. Kyl). But consider how the legislation evolved:

2005 "(1) the claimed invention was patented, described in a printed publication, *or otherwise publicly known*" (H.R. 2795)

[redacted]

2008 "(1) the claimed invention was patented, described in a printed publication, *or otherwise made available to the public (other than through testing undertaken to reduce the invention to practice)*" (S. 3600)

[redacted]

Thus, from 2005 to 2008, the bills eliminated the on-sale bar. By 2011, however, it was back to stay, prompting Senator Kyl and two others to object that Congress had put "non-public" uses back into the definition of prior art. S. Rep. No. 111–18, at 60 (2009).

After losing in committee, some senators took to the floor, announcing that the new §102 did not mean

what it said. But their statements are "strategic manipulations of legislative history to secure results [members] were unable to achieve through the statutory text." *Exxon Mobil Corp.* v. *Allapattah Services, Inc.*, 545 US 546, 568 (2005); see Merges & Duffy, *supra*, at 361 (calling Senator Kyl's statements "wishful thinking"). Courts may "not assume that Congress intended to enact statutory language that it has earlier discarded." *Chickasaw Nation* v. *United States*, 534 U.S. 84, 93 (2001). Rather, when Congress rejects "the very language that would have achieved the result [that a party] urges," that "weighs heavily against [its] interpretation." *Hamdan* v. *Rumsfeld*, 548 U.S. 557, 579–580 (2006).

2. Rather than grapple with the drafting history, Helsinn presses floor statements (Pet. 21), as it did below, prompting Teva to reply that "the statutory text" is "authoritative" (C.A. Br. 21–22). The Federal Circuit agreed that "floor statements are typically not reliable," but considered them at Helsinn's insistence. Pet. 36a. The court's caution was warranted, as "even a bill's sponsor['s views] are not controlling." *Mims* v. *Arrow Fin. Servs., LLC*, 132 S. Ct. 740, 752 (2012); cf. *Exxon*, 545 U.S. at 568 (same for "committee reports").[3]

Even the floor statements, however, "[a]t most" voiced concern with "extreme" cases holding "certain secret uses to be invalidating under the 'public use' [bar]"; they "do not identify any sale cases that would be overturned." Pet. 37a–38a. No legislators "in-

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[3] Helsinn cites the House Committee Report (Pet. 7), but it referenced Senate floor statements for the unrelated fact that the "'current law's grace period' 'is maintained.'" H.R. Rep. No. 112-98, at 43 & n.20 (2011).

dicat[ed] that they intended to allow parties who have exploited inventions as trade secrets for years to be able nonetheless to patent those inventions." Merges & Duffy, *supra*, at 361. Further, "[e]ven if the floor statements were intended to overrule th[e] secret or confidential sale cases," "that would have no effect here since those cases were concerned entirely with whether the existence of a sale or offer was public." Pet. 38a. Thus, Helsinn's approach to legislative history—cherry-picking floor statements while ignoring the drafting history—fails on its own terms.

D. Two centuries of this Court's precedents and the Constitution confirm that the on-sale bar is triggered by all types of sales.

Under centuries of precedent, the decision below would be correct even if the sale here were secret. This Court has repeatedly held that the Patent Act and the Constitution bar commercially exploiting inventions before patenting them.

In the leading decision, which predates the on-sale bar, this Court invalidated a patent on a process of making hose with improved joints, where the inventor had earlier authorized sales of the hose. *Pennock*, 27 U.S. at 3, 9. Although the sales did not disclose the claimed process, the Court held that where an inventor allows the invention "to be publicly sold for use, before he makes application for a patent," that "creates a disability to comply with the terms and conditions on which [the government] is authorized to grant him a patent." *Id.* at 24.

The Court relied heavily on the Constitution, which requires reading the patent laws to "promote the progress of science" and secure patents only for "*limited times*." *Id.* at 16 (Story, J.) (quoting U.S.

Const. Art. I, § 8, cl. 8). If inventors could profit from their inventions while "hold[ing] back from the knowledge of the public the[ir] secrets"—but patent them later—that "would materially retard the progress of science" and "give a premium to those who should be least prompt to communicate their discoveries.'" *Id.* at 19.

Later, in *Kendall*, this Court held that an "inventor who designedly, and with the view of applying [his invention] indefinitely and exclusively for his own profit, withholds his invention from the public, comes not within the policy or objects of the Constitution or acts of Congress." 62 U.S. at 328. Further, *Pfaff* reaffirmed *Pennock* and later cases, stating that "[a]ny attempt to use [an invention] for a profit, and not by way of experiment, for a longer period than [the prescribed grace period] before the application, would deprive the inventor of his right to a patent." 525 U.S. at 65 (quoting *Elizabeth* v. *Am. Nicholson Pavement Co.*, 97 U.S. 126, 137 (1877)). Thus, "it is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." *Pfaff*, 525 U.S. at 68 (quoting *Metallizing*, 153 F.2d at 520).

Helsinn never acknowledges that its reading of the AIA would require overruling the *Pennock* line of cases and eviscerate the Patent Act's only language preventing private commercial exploitation of inventions before patenting. See Pet. 39a–40a (discussing *Pennock*); Pet. 13a–14a (O'Malley, J.) (citing *Pfaff*'s statement that "the 'overriding' concern [of the on-sale bar] is the risk that an inventor will commercially exploit his invention beyond the statutory term"); *Continental Plastics*, 141 F.3d at 1079. Indeed, Hel-

sinn attempts to recast the on-sale bar as existing solely to protect what is "in the public domain." Pet. 27. But under this Court's longstanding view, expressed in cases such as *Pfaff*, the on-sale bar prevents exactly what Helsinn attempted to do here—extend its commercial monopoly.

Helsinn assures the Court that "under the AIA's first-inventor-to-file system," "[a]n inventor cannot secretly exploit its invention while waiting for competition to come along because the competition might beat the first inventor to the Patent Office." Pet. 24. As *Pennock* and *Metallizing* confirm, however, many inventions—especially manufacturing processes—are "easily conceal[ed]." Lemley, *supra*, at 1132. Thus, inventors "could keep their process inventions secret for years or even decades and then surface and file a patent application." *Ibid.* The prospect of that revolutionary change in the law may explain the presence of Helsinn's pro-patentee amici—most of whom are industry stakeholders who stand to gain from indefinite monopolies. Indeed, even Congressman Smith is represented by Eli Lilly's former general counsel.

"If one of [two plausible statutory constructions] would raise * * * constitutional problems, the other should prevail." *Clark* v. *Martinez*, 543 U.S. 371, 380–381 (2005). Here, allowing inventors to exploit inventions privately before patenting them would upend venerable policy and violate the Constitution.

E. Helsinn's policy arguments do not support review.

Helsinn's policy arguments would not justify certiorari even if they had merit. But they do not.

1. Helsinn says the ruling below conflicts with Congress's elimination of "territorial restrictions"

that "restricted disqualifying sales to those occurring in the United States." Pet. 25. That is no reason to think the meaning of "sale" changed. Secret overseas sales will rarely invalidate patents, and regardless the geographic limitation is unnecessary "[g]iven advances in communications technology and transportation" that provide knowledge "about activities in a foreign land." H.R. Rep. No. 110–314, at 57 (2007).

2. Helsinn complains that the ruling could harm "small" companies that rely on pre-launch confidential distribution agreements and have regulatory disclosure obligations. Pet. 5, 29–31. But even if Helsinn were small—it has over $500 million in annual revenue and products "in approximately 190 countries"[4]—such companies can avoid the bar by applying for patents for up to a year after any sale. See also Pet. 7a (O'Malley, J.). As the court below held, the "completion of Phase III studies and final FDA approval are not pre-requisites for the invention here to be ready for patenting"; and Helsinn's data "showed that the invention worked," from "the 1995 Phase II trial" onward. Pet. 47a, 51a. Thus, Helsinn's difficulty was caused by its own delay.

3. Helsinn next says the decision, by requiring searches for foreign sales, interferes with Congress's desire for "more efficient" post-grant review. Pet. 25. But Congress's purpose in amending a ground of invalidity applied primarily by courts and examiners was not driven by what would be most convenient for post-grant proceedings, and courts are not "simplistically to assume that whatever furthers" one "[statu-

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[4] https://www.helsinn.com/news-and-events/helsinn-pharmaceuticals-beijing-co-ltd-opens-office-in-shanghai-china/.

tory] objective must be the law." *Rodriguez* v. *United States*, 480 U.S. 522, 526 (1987).

4. Nor will the decision below thwart Congress's goal of "harmoniz[ing]" prior-art rules with international practice. Pet. 23. The AIA harmonized U.S. and foreign law in some ways, but not others. For example, some "foreign patent systems" lack "grace period[s]," but Congress provided "a significant number" of grace periods. Merges, *supra*, at 1032 & n.25, 1030. Finally, it harmonizes U.S. and foreign law to read the "otherwise available" clause to capture disclosures not "described in a printed publication."

CONCLUSION

For the foregoing reasons, the petition for certiorari should be denied.

Respectfully submitted.

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MAY 2018

APPENDIX

APPENDIX

NOTE: This order is nonprecedential.

United States Court of Appeals
for the Federal Circuit

HELSINN HEALTHCARE S.A.,
Plaintiffs-Appellees

v.

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Defendants-Appellants

2016-1284, 2016-1787

Appeals from the United States District Court for the District of New Jersey in Nos. 3:11-cv-03962-MLC-DEA, 3:11-cv-05579-MLC-DEA, 3:13-cv-05815-MLC-DEA, Judge Mary L. Cooper.

ON MOTION TO STAY MANDATE

Before DYK, MAYER, and O'MALLEY, *Circuit Judges*. PER CURIAM.

ORDER

The motion to stay is denied. The parties agree that granting a stay requires finding, at least, (1) "a reasonable probability that the Supreme Court will grant *certiorari*; [and] a reasonable possibility that at least five Justices would vote to reverse this Court's judgment," and (2) "a likelihood of irreparable injury" to the moving party. *Nara v. Frank*, 494 F.3d 1132, 1133 (3d Cir. 2007); *see also Doe v. Miller*, 418 F.3d 950, 951 (8th Cir. 2005); *United States ex rel. Chandler v. Cook County*, 282 F.3d 448, 450 (7th Cir. 2002) (Ripple, J., in chambers).

For the reasons set forth in the majority opinion, and in Judge O'Malley's concurrence to the denial of rehearing, the decision is a narrow one. There also has been no showing of irreparable injury. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 134 S. Ct. 1621, 1621 (2014) (Roberts, Circuit J.)

IT IS ORDERED THAT:

The motion is denied. Pursuant to Rule 41(b) the mandate will issue seven days from the date of this order.

FOR THE COURT

January 22, 2018

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court